510(K) Summary K063334

Submitter
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DEC - 8 2006

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Date Nov.6, 2006

Trade Name
Shanghai Ganghai Purifying Products Co. Ltd. Type N-95 Healthcare Particulate Respirator and Surgical Mask Model GIKO 1400

Common Name:
Healthcare Particulate Respirator and Surgical Mask

Classification
Device Class - Class II
CFR Section – 21 CFR 878.4040

Substantial Equivalency:
The Model GIKO 1400 Heathcare Particulate Respirator and Surgical Mask is found to be substantially equivalent to the Gerson Model 2130 Type N95 Mask . (510(K) No. K050193. Both products have been tested and approved by NIOSH as N-95 respirators.

USE

Description:

The Shanghai Ganghai Type N95 Healthcare Particulate Respirator and Surgical Mask Model GIKO 1400 is of a duckbill style.It constructed from a white nonwoven material used in the inner and outer shell. The polypropylene melt blown filter media is layered between the inner and outer shell. The headband is made of elastic rubber . The inside nosepiece utilizes a closed cell foam and the outside nosepiece which conforms to the nose is made of plastic coated aluminum.

Description of Device Requirements

The Shanghai Ganghai Type N95 Healthcare Respirator and Surgical Mask Model GIKO !400 is approved by NIOSH as per 42 CFR 84. The certification number assigned is TC-84A-4282 for a type N95 Particulate Respirator. The Type N95 must meet the prescribed test criteria which specifies the use of 0.3 micron diameter challenge and requiring a 95% efficiency. This mask is resistant to synthetic blood as per ASTMF1862-00 Standard Test Method for Resistance of Medical Face Mask to Penetration by Synthetic Blood, conducted by Nelson Laboratories. Breathing resistance was tested as per NIOSH 30 CFR11 section 11.140-9. Flammability testing as per16CFR Part1610 was conducted by Nelson Laboratories.

Intended Use:

The Shanghai Ganghai Type N95 Healthcare Particulate Respirator and Surgical Mask Model GIKO 1400 is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

This device also meets CDC Guidelines for TB Exposure Control.

Limitations:

This product does not eliminate the wearer from any risk of contracting any type of disease or infection. The mask should be changed immediately if contaminated with blood or body fluids.

Comparison of Predicate Device

The outside cover stock color of the previously cleared device is white. The Shanghai Ganghai Model GIKO 1400 Healthcare Particulate Respirator and Surgical Mask Model is also white. The headband color of the cleared device is yellow and the Shanghai Ganghai Model GIKO 1400 is white.

The Shanghai Ganghai Model GIKO 1400 Healthcare Particulate Respirator and Surgical Mask incorporates a highly efficient filter media and is 95% efficient against a .3 micron particulate which was scientifically established as the most penetrating particle size. The legally marketed Gerson device previously cleared 510 (k) K050193 NIOSH T C – 84A-4123 is manufactured from similar materials.

Risks to Health

The FDA Guidance Document was used to identify the risks to health associated with the use of surgical masks. The device was tested as per the mitigation measures listed below.

Identified Risk	Mitigation Measures
Inadequate fluid resistance	ASTM F1862
Inadequate barrier for bacteria	NIOSH TC-84A-4282
Inadequate air exchange	NIOSH TC-84A-4282
Flammability	16CFR Part 1910
Biocompatibility for patient/user contacting materials	Cytotoxicity Agar Overly Sensitization Buehler Method

Safety/Effectiveness

The device has a filtration equivalent to the previously cleared Gerson 2130 Healthcare Particulate Respirator and Surgical Mask Respirator. It is NIOSH approved and meets the CDC guidelines for TB Exposure Control. The GIKO 1400 was subjected to the tests listed and passed.

Conclusion:

Since the basic construction is used in the FDA cleared device as in the new device and approved by NIOSH, the GIKO 1400 Shanghai Ganghai Healthcare Particulate Respirator and Surgical Mask is substantially equivalent to the Gerson Model 2130 Healthcare and Particulate Respirator and Surgical Mask

Physical Characteristics

MATERIALS

Part	*GIKO 1400*	*Gerson2130*
Inside Shell	Nonwoven	Nonwoven
Filter	Nonwoven	Nonwoven
Outside Shell	Nonwoven (White)	Nonwoven (White)
Headband	Elastic (White)	SyntheticRubber (Yellow)
Inside Nosepiece	Closed Cell Foam	Closed Cell Foam
Outside Nosepiece	Plastic Coated Aluminum	Plastic Coated Aluminum

Physical Measurements

Physical Attributes	*GIKO 1400*	*Gerson 2130*
Mask Thickness	0.038 Inches	0.037 Inches
Surface Area	27.0 Square inches	27.0 Square inches
Headband Length	24 Inches Total Continuous Loop	12 Long 10 Short Inches
Facepiece Length	7.0 Inches	7.0 Inches

Mask Style

GIKO 1400	*Gerson 2130*
Duck Bill	Duck Bill

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Shanghai Gangkai Purifying Products Corporation, Limited
C/O Mr. Joseph Z. Zdrok
Consultant
7380 36th Court
Vero Beach, Florida 32967

Re: K063334
Trade/Device Name: Shanghai Ganghai Type N95 Model GIKO 1400 Healthcare Particulate Respirator and Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: MSH
Dated: November 28, 2006
Received: November 29, 2006

Dear Mr. Zdrok:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K06834

Device Name: Shanghai Ganghai Type N95 Model GIKO 1400 Healthcare Particulate Respirator and Surgical Mask

Indications for Use:

The Shanghai Ganghai Model GIKO 1400 Healthcare Particulate Respirator and Surgical Mask is a NIOSH approved N95 single use, disposable, LATEX FREE, non-sterile product. It is a non-fiberglass, fluid resistant mask intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids and particulate material. This device also meets CDC Guidelines for TB Exposure Control.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ✓ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

11/21/2006